

PPTA Comments on Recovered Plasma

FDA's Plasma Standards Workshop
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- Supports AABB Task Force Recommendation
- Recommends that Source Plasma definition not be changed
- Cautions against use of meaningless metrics
- Requests consideration of specialty immunoglobulins when assigning expiry

- AABB Task Force Recommendation
 - Achievable by redefining Plasma in 21 CFR 640.30(a) to include intended use for manufacturing as well as transfusion
 - Allows definition of Source Plasma in 21 CFR 640.60 to remain
- Distinction in products based on frequency of collection and associated donor monitoring provisions

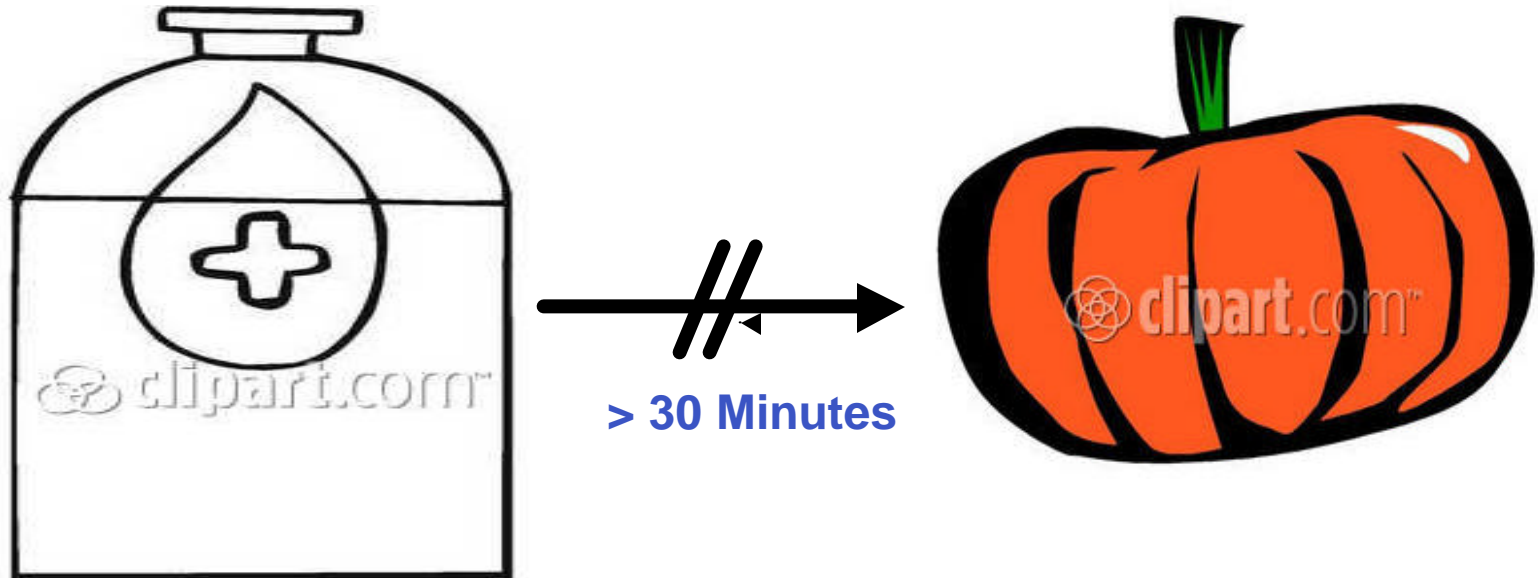
- In codifying standards, beware of metrics that are unachievable or overly specific:
 - 21 CFR 640.69(b)— “Immediately after filling, plasma intended for manufacturing into injectable products shall be stored. . .”
 - “Immediately” is not achievable
 - “Guide to Inspections of Source Plasma Establishments” interprets “‘immediately’ means ‘without undue delay’”
 - Another interpretation of “immediate” has been “30 minutes”
 1. 30 minutes has become an absolute
 2. Measurable and actionable

Recovered Plasma Comments



- Cinderella's fairy godmother warns her not to stay at the ball past midnight.
- Violating this measurement has real consequences for Cinderella.

Recovered Plasma Comments



- Plasma does not turn into a pumpkin if not in the freezer within 30 minutes
- Metric targets should not become absolute requirements

- Source Plasma expiration dating is 10 years
 - Dating has been shortened by fractionators
 - Shortened expiry due to inventory management and changes in testing, not stability
- 2 – 3 years may be adequate for most uses
- AABB is recommending 2 years
- Specialty immunoglobulins may require longer expiration dating. Regulation should remain at maximum dating.

- Supports AABB Task Force Recommendation
- Recommends that Source Plasma definition not be changed
- Cautions against use of meaningless metrics
- Requests no change in Source Plasma expiration